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| APPLICATION NO.                    | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/599,448                         | 03/08/2007  | Pascal Drevet        | 033339/317269       | 9114             |
| 826                                | 7590        | 09/29/2011           | EXAMINER            |                  |
| ALSTON & BIRD LLP                  |             |                      | SNYDER, STUART      |                  |
| BANK OF AMERICA PLAZA              |             |                      |                     |                  |
| 101 SOUTH TRYON STREET, SUITE 4000 |             |                      | ART UNIT            | PAPER NUMBER     |
| CHARLOTTE, NC 28280-4000           |             |                      | 1648                |                  |
|                                    |             |                      |                     |                  |
|                                    |             |                      | MAIL DATE           | DELIVERY MODE    |
|                                    |             |                      | 09/29/2011          | PAPER            |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/599,448             | DREVET ET AL.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | STUART W. SNYDER       | 1648                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1)  Responsive to communication(s) filed on 23 August 2010.
- 2a)  This action is **FINAL**.                            2b)  This action is non-final.
- 3)  An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 5)  Claim(s) 35-53,55-57 and 67-79 is/are pending in the application.
  - 5a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 6)  Claim(s) \_\_\_\_\_ is/are allowed.
- 7)  Claim(s) 35-53,55-57 and 67-79 is/are rejected.
- 8)  Claim(s) \_\_\_\_\_ is/are objected to.
- 9)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 10)  The specification is objected to by the Examiner.
- 11)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All    b)  Some \*    c)  None of:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ .  | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/23/2010 has been entered.

### ***Status of the Claims***

2. Claims 35-53, 55-57 and 67-79 are pending and examined herein. Amendment of claim 35, 44 and 52; and cancellation of claim 79 is acknowledged.

### ***Claim Rejections - 35 USC § 102***

3. Rejection of claims 35-37, 42 and 48 under 35 U.S.C. 102(b) as being anticipated by Hakansson and Caffrey is **withdrawn** in view of amendment of the claims.

### ***Claim Rejections - 35 USC § 103***

4. Rejection of claims 55-57 under 35 U.S.C. 103(a) as being unpatentable over Hakansson and Caffrey in view of Linblad is **withdrawn** in view of amendment of the claims.
5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. In view of the Examiner's uncertainty as to whether or not

the cited art meets the functional limitation of the claims, the art is not applied in the instant Office Action.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 35-53, 55-57 and 67-79 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 35 recites, *inter alia*, "a stabilized Tat antigen resistant to proteolytic degradation...wherein one to seven cysteines located at positions 22, 25, 27, 30, 31, 34, and/or 37 of the Tat amino acid sequence are modified by...leucine, isoleucine, methionine, phenylalanine, tryptophan, tyrosine and the hydrophobic analogs of said amino acids". The specification exemplifies the claimed subject matter demonstrating that certain species of modified tat-encoded polypeptide are resistant to proteolytic cleavage by at least chymotrypsin and is presented on page 44, Table 1 of the filed specification. the variants of the tat-encoded polypeptide resistant to chymotrypsin cleavage are those in which all seven cysteine residues recited in the claim are mutated to leucine, phenylalanine or tryptophan; the cys-ser modification is less resistant to

chymotrypsin proteolysis. It is reasonable to assume that isoleucine and tyrosine are likewise chymotrypsin resistant because of the close similarity of these amino acids to leucine and phenylalanine, respectively. However, methionine is an isomer of serine and would therefore be likely to be less stable to proteolytic cleavage by chymotrypsin. Other non-liganded modification of the tat-encoded polypeptide resistant to chymotrypsin-dependent proteolysis the StBu-modified specie and the triple mutated, StBu-modified tat-encoded specie. With that single exception, there are no examples in the specification for cysteine mutations in which less than all seven cysteines mutated nor are there examples in the specification of any species of tat-encoded polypeptide in which all seven of the recited cysteines are not either mutated or derivitized by StBu. Thus, it is *prima facie* evident that Applicant did not possess the entire scope of the claimed invention.

***Conclusion***

7. No claims are allowed.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to STUART W. SNYDER whose telephone number is (571)272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ZACHARIAH LUCAS can be reached on (571)272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachariah Lucas/  
Supervisory Patent Examiner, Art Unit 1648

STUART W SNYDER  
Examiner  
Art Unit 1648

SWS